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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,237	04/05/2006	Evelyne Lopez	3665-170	6246

23117 7590 11/16/2007  
NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER
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ARIANI, KADE

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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11/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/561,237

Applicant(s)

LOPEZ ET AL.

Examiner

Kade Ariani

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***DETAILED ACTION***

The amendment filed on 08/20/2007, has been received and entered.

Claims 16-29 are pending in this application and were examined on their merits.

***Claim Objections***

The objection is withdrawn due to applicant amendments to the claims filed on 08/20/2007.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 28 and 29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn due to applicants amendments to the claims filed on 08/20/2007.

Applicant's arguments filed 08/20/2007 have been fully considered but they are not persuasive.

***Claim Rejections - 35 USC § 102/103***

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Claim 16-29 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chamlin et al. (J. Am. Acad. Dermatol. 2002, Vol. 47, No.2, p. 198-208).

Claims 16-29 are drawn to a composition comprising lipids and a pharmaceutically acceptable support, suitable for topical application, the composition further comprises at least one other therapeutically active ingredient.

Chamlin et al. discloses a pharmaceutical composition comprising lipids, ceramides, free fatty acids, and cholesterol (p.199, 2<sup>nd</sup> column, 3<sup>rd</sup> paragraph, lines 9-12) for topical application, used as adjunct (topical corticosteroids) for the treatment of childhood atopic dermatitis (see Abstract & Discussion, column 2, lines 14-19), and a concentration between 0.02% and 3% by weight (p.199, column 2, lines 51-54).

It is noted that Chamlin et al. do not state a lipid extract obtained by extraction from the mother of pearl. Please note that the aim of all lipid extraction procedures is to separate lipids from other constituents. Chamlin et al. describes a pharmaceutical composition comprising lipids, the claimed lipids appear to be the same to that of the prior art, and therefore it must necessarily have the claimed properties. Note that applicant's claims simply require that the lipids be an extract from mother of pearl mollusks and applicant defines those lipids on page 7-8 of the specification to include ceramides, cholesterol and "fatty acids." As the only description of the "extract" is what is disclosed in this section of the specification, the prior art disclosure of cholesterol, fatty acids and ceramides must be considered to anticipate the claimed invention.

Furthermore, claims 16-29 are drawn to a composition comprising a lipid extract, and therefore are product-by-process claims, and the recitation "for the treatment of pathologies involving a decrease in flilaggrin activity..." is an intended use and does not impart structural differences between prior art and the claimed invention.

Applicant argues that the lipid extract has a lipid content which is specific and is considerably different from the composition of Chamlin et al, and the lipid content of the lipid extract of the invention is not anticipated and would not have been obvious from the composition of Chamlin et al.

However, Chamlin et al. disclose a pharmaceutical composition comprising, ceramides, free fatty acids, and cholesterol. Chamlin et al. further disclose optimal barrier function requires the presence of sufficient extracellular lipids to form a competent lamellar bilayer system, and barrier abnormality correlates with a global reduction in these stratum corneum lipids (p.199, 1<sup>st</sup> column 2<sup>nd</sup> paragraph). Please note that stratum corneum lipids are composed of ceramides, cholesterol, free fatty acids, cholesterol esters, and cholesterol sulfate.

Applicant argues that the extract indicated on page 7-8 of the present application also contains cholesterol sulfate, triglycerides, cholesterol acetate, apolar lipids, which is the main component of the extract.

However, claims are directed to a composition comprising a lipid extract and not to specific lipid content of the extract, or to cholesterol sulfate, triglycerides, cholesterol acetate, and apolar lipids.

Therefore Chamlin et al. clearly anticipated the claimed invention.

***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

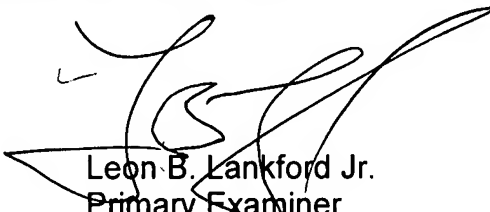
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani  
Examiner  
Art Unit 1651



Leon B. Lankford Jr.  
Primary Examiner  
Art Unit 1651